

PCT / IB 0 4 / 0 0 9 0 1

0 4 MAR 2004

MAILED 3 1 MAR 2004

WIPO

PCT

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

February 17, 2004

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

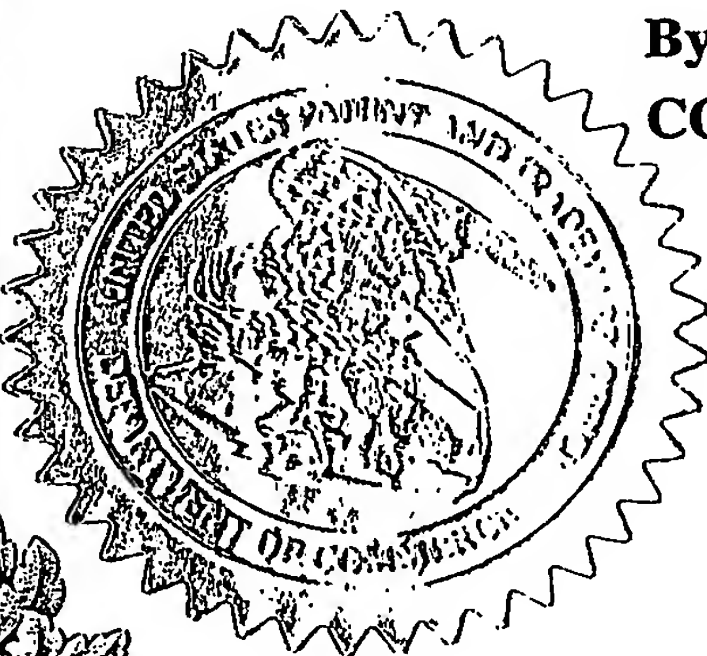
APPLICATION NUMBER: 60/458,796

FILING DATE: *March 28, 2003*

## PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS



*L. Edelen*

L. EDELEN  
Certifying Officer

BEST AVAILABLE COPY

03/28/03



JC891 U.S. PTO

Please type a plus sign (+) inside this box



03-31-03

60458796 032803

PTO/SB/18 (02-01)

Approved for use through 10/31/2002. OMB 0851-0032  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**PROVISIONAL APPLICATION FOR PATENT COVER SHEET**

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No. EL827840990US Date of Deposit: March 28, 2003

INVENTOR(S)					
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)			
Daniel A.	Silber	Lexington, MA			
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
DUAL ELECTRODE WITH THREE STUDS FOR IMPEDANCE CARDIOGRAPHY					
CORRESPONDENCE ADDRESS					
Direct all correspondence to:					
<input checked="" type="checkbox"/> Customer Number		24737			
OR		Type Customer Number here		<div style="border: 1px solid black; padding: 5px; text-align: center;">*24737*</div>	
<input type="checkbox"/> Firm or Individual Name					
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		15		<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		3		<input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 14-1270				160.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

Date

26 March 2003

TYPED or PRINTED NAME

Tony E. Piotrowski

REGISTRATION NO.: 42,080  
(if appropriate)

TELEPHONE

(914) 333-9609

Docket Number: US030071

**USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT**

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

JC891 U.S. PTO

60/458796



Docket No. US030071

DUAL ELECTRODE WITH THREE STUDS FOR IMPEDANCE  
CARDIOGRAPHY

5 BACKGROUND OF THE INVENTION

1. Field of Invention

The present invention relates to medical electrodes.  
More particularly, the present invention relates to  
medical electrodes that can be used in impedance  
10 cardiography.

2. Description of the Related Art

Impedance cardiography (ICG) is a medical test to  
determine the pumping capacity of the heart. ICG is a  
15 non-invasive and cost-efficient technique for determining  
stroke volume (SV), cardiac output (CO), and thoracic  
fluid volume (TFC, or ZO). Impedance cardiography is  
also referred to as "Non-Invasive Continuous Cardiac  
Output" (NiCCO). Impedance cardiography also provides  
20 the physician with a measurement of cardiac output  
without the need for catheterization, an invasive  
procedure that is expensive and poses some risk to the  
patient.

ICG normally requires four pairs of electrodes, each  
25 pair spaced approximately 50 mm apart. Existing products

Docket No. US030071

in the prior art require separate cable connections for each of the electrodes.

To date, there is one double electrode being used  
5 for impedance cardiography by CardioDynamics of San Diego, California. This product has two sensing elements, separated by 50 mm, each electrode connected directly to the same size snap stud. The prior art also includes single-electrode sensors which have offset studs. In  
10 some cases, the offset was done to minimize migration of corrosive coupling agents. In other cases, a single electrode was provided to make two connection points.

However, there is a need in the art for an electrode structure that permits electrodes to be connected quickly  
15 without separate cables.

#### SUMMARY OF THE INVENTION

The present invention provides a disposable medical electrode pair with an additional stud that is mounted  
20 near one stud but is electrically connected to the other, thus bringing the two connection points close together and allowing the pair of electrodes to be connected simultaneously with a two-conductor connector. In other words, instead of requiring a dual connector to be larger  
25 than the (50 mm) distance between the two electrodes, the

Docket No. US030071

current dual electrode assembly permits use of a much smaller connector that is only slightly larger than the distance between the proximal stud and the additional stud, yet keeps the electrodes on the patient side spaced at the optimal distance.

According to an aspect of the invention, the arrangement of the two connections close together advantageously allows the simultaneous connection of both, which permits increased speed of installation and convenience to the practitioner. Such increased speed and convenience can be critical, especially since this invention could be used on patients requiring emergency life-saving care. Accordingly, the increased speed and convenience is extremely desirable.

In addition, the arrangement of the two connections close together allows securing the two wires to each other, reducing the tendency of the capacitance between the wires to change and create electrical noise.

Moreover, the arrangement of the two connections together makes the system less intrusive for the patient, so it appears to the patient that four connections are being made instead of eight.

According to an aspect of the invention, the medical electrode or sensor preferably would be disposable.



Docket No. US030071

Making the double electrode more convenient to use also discourages users from substituting individual standard ECG electrodes, a practice that would introduce  
5 variability into the test results.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1a illustrates a patient-side perspective of an aspect of the electrode apparatus according to the  
10 present invention.

Fig. 1b illustrates a cross-section view of the electrode apparatus shown in Fig. 1a.

Fig. 1c illustrates a cable-side perspective of an aspect of the electrode apparatus according to the  
15 present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

It is understood by persons of ordinary skill in the art that the illustrations and description herein are  
20 provided for purposes of explanation, and the claimed invention is not limited to the embodiments shown and described, as an artisan can make variations in the design that lie within the spirit of the invention and the scope of the appended claims.

Docket No. US030071

Fig. 1a shows the patient side of an electrode apparatus according to the present invention. The body of electrode 100, in a best mode, would comprise a pressure sensitive adhesive-coated foam similar to that used in other electrodes. However, a solid gel 101, 102 (shown in Fig. 1a) is preferred over a liquid gel. A liquid gel would be poured into the cavities in the assembly after the studs, label, etc. are assembled to the foam. The gel sections 101, 102, each of which may be a differing size and shape, adhere to the eyelets (base) 101a, 102a, each part of a snap assembly, which are secured to the foam base when the stud parts 106, 108 of the assembly are pressed on.

Adhesive on the label 103 secures it to the foam 100, as holes in the foam form wells for the gels.

The distal snap assembly 101a, 108 includes an eyelet 101a and a distal stud 108, and the distal snap assembly also secures one end of an electrically-conductive jumper 104 and may be covered by an electrically insulating cap 107 of various designs. The electrically-conductive jumper may be made from foil, plated plastic, or other material or even printed on the label, and may include an insulating layer if required.

Docket No. US030071

The additional snap assembly 105a, 105 includes eyelet 105a and additional stud 105, and this assembly secures the proximal end of the jumper, but it is electrically isolated from the patient. This is achieved by securing it to the label, without penetrating the foam, or by using a non-conductive eyelet 105a (Fig. 1a) or by other means. The final result is two solid gel sections 101, 102 on the patient side (shown in Fig. 1a.) arranged substantially 50 mm apart, and an additional stud 105 located substantially 15 mm from proximal stud 106 and 35 mm from distal stud 108 (Fig. 1c).

The connections are preferably made to the additional stud 105 and to the proximal stud 106, approximately 15 mm from it. Ideally, the additional stud 105 can be a different size than the proximal and distal studs 106, 108 that hold the electrode gels, thus precluding inadvertent exchange of the two connections. Ideally, the connector on the cable side can conveniently make both connections simultaneously.

Some of the many aspects of the instant invention, in addition to those previously mentioned in the summary of the invention, include that the electrode is compatible with a very inexpensive cable if it is necessary to forego a double connector type cable for a



Docket No. US030071

lower-cost cable with separate connectors, in which case,  
the stud cover 107 is removed, preferably without the  
need for tools, and discarded. Then connections are made  
5 to the distal stud 108 and the proximal stud 106 using  
commonly available snap fittings or grabber fittings,  
which are generally used on ECG cables.

Various modifications can be made to the instant  
invention by persons of ordinary skill in the art that  
10 would not depart from the spirit of the invention or the  
scope of the appended claims. For example, the distances  
between the studs, although currently proposed so as to  
be compatible with certain medical standards, could be  
varied. The shape and/or size of the studs, etc. can be  
15 different from those previously shown. The relative sizes  
of the studs can also be different. Other types of  
fittings could be substituted, and such fittings also  
would not depart from the spirit of the invention and the  
scope of the appended claims.

Docket No. US030071

What is claimed is:

1. A quick connecting dual electrode assembly comprising:

a body having a cable side and a patient side, and three eyelets arranged in said body;

a distal snap assembly comprising a distal stud securing a first eyelet of said three eyelets near an end of the body, and an additional stud securing a second eyelet arranged near a center of the body, wherein said distal stud and said additional stud are electrically joined by a jumper assembly;

a proximal snap assembly comprising a proximal stud securing a third eyelet at an opposite end from where said distal stud is arranged proximal to the additional stud, so that a distance between said proximal stud and said additional stud is substantially less than a distance between said distal stud and said proximal stud;

wherein said additional stud is electrically isolated from said patient side.

2. The electrode assembly according to claim 1, wherein said second eyelet is non-conductive.

Docket No. US030071

3. The electrode assembly according to claim 1, wherein an external surface of the body is coated with an adhesive.

4. The electrode assembly according to claim 1, wherein the patient side of the body includes a first solid gel portion 101 that adheres to the first eyelet and a second solid gel portion that adheres to the second eyelet.

5. The electrode assembly according to claim 1, wherein the patient side of the body includes a first liquid gel portion that adheres to the first eyelet and a second liquid gel portion that adheres to the second eyelet, and the first liquid gel portion and the second liquid gel portion are about 50mm apart.

6. The electrode assembly according to claim 1, wherein the jumper assembly comprises foil.

7. The electrode assembly according to claim 1, wherein the jumper assembly comprises plated plastic.

Docket No. US030071

8. The electrode assembly according to claim 6, wherein the jumper assembly has a label printed thereon.

9. The electrode assembly according to claim 1, wherein the distance between said distal stud and said additional stud is about 35mm apart.

10. The electrode assembly according to claim 9, wherein the distance between said distal stud and said proximal stud is about 50mm.

11. The electrode assembly according to claim 9, wherein the distance between the additional stud and the proximal stud is about 15mm.

12. The electrode assembly according to claim 1, wherein electrical connections are made on the cable side of the body to the additional stud and the proximal stud.

13. The electrode assembly according to claim 12, wherein the additional stud is a different size than the proximal stud and the distal stud.

Docket No. US030071

14. The electrode assembly according to claim 1, wherein the additional stud has a heart shaped label arranged on its outer perimeter on the patient side of the body.

15. The electrode assembly according to claim 1, wherein the distal stud has a removable cover.

16. The electrode assembly according to claim 15, wherein the cover is electrically insulating.

17. The electrode assembly according to claim 1, wherein the additional stud and proximal stud are sized to receive a two-stud connector plug thereon.

18. A method of making a dual-electrode assembly comprising the steps of:

(a) providing a body having a cable side and a patient side, and three eyelets arranged in said body;

(b) providing a distal snap assembly comprising a distal stud securing a first eyelet of said three eyelets near an end of the body, and an additional stud securing a second eyelet arranged near a center of



Docket No. US030071

the body, wherein said distal stud and said additional stud are electrically joined by a jumper assembly;

(c) providing a proximal snap assembly comprising a proximal stud securing a third eyelet at an opposite end from where said distal stud is arranged and proximal to the additional stud, so that a distance between said proximal stud and said additional stud is substantially less than a distance between said distal stud and said additional stud; and

(d) isolating said additional stud from said patient side.

19. The method according to claim 18, further comprising:

(e) arranging a first solid gel portion on the patient side of the first eyelet; and

(f) arranging a second solid gel portion on the patient side of the second eyelet, so that said first gel portion and said second gel portion are about 50mm apart.

20. The method according to claim 18, further comprising:

(e) sizing the additional stud at a different diameter than the distal stud and the proximal stud.

Docket No. US030071

21. The method according to claim 20, wherein the diameter of the additional stud is larger than at least one of the proximal stud and the distal stud.

22. The method according to claim 18, further comprising (e) shaping the additional stud in a different shape than at least one of the proximal stud and the distal stud.

Docket No. US030071

ABSTRACT OF THE DISCLOSURE

A quick-connecting dual electrode assembly for use in procedures such as impedance cardiography includes a body  
5 having a cable side and a patient side, and three eyelets arranged therein. A distal snap assembly having a distal stud is secured in a first eyelet of said three eyelets near an end of the body. An additional stud is arranged in a second eyelet near a center of the body, wherein the  
10 distal stud and the additional stud are electrically joined by a jumper assembly. A proximal snap assembly having a proximal stud secured in a third eyelet at an opposite end from where the distal stud is arranged proximally to the additional stud, so that a distance  
15 between the proximal stud and the additional stud is substantially less than a distance between the distal stud and the additional stud. The additional stud is electrically isolated from the patient side, and a gel portion is arranged on the patient side of the body for  
20 the first stud and the third stud. The electrode apparatus facilitates quick connection of a small dual plug so that the dual plug does not have to be the length of the distance between the two electrically connected studs, yet keeps the electrodes in contact with the  
25 patient at an optimum distance apart.

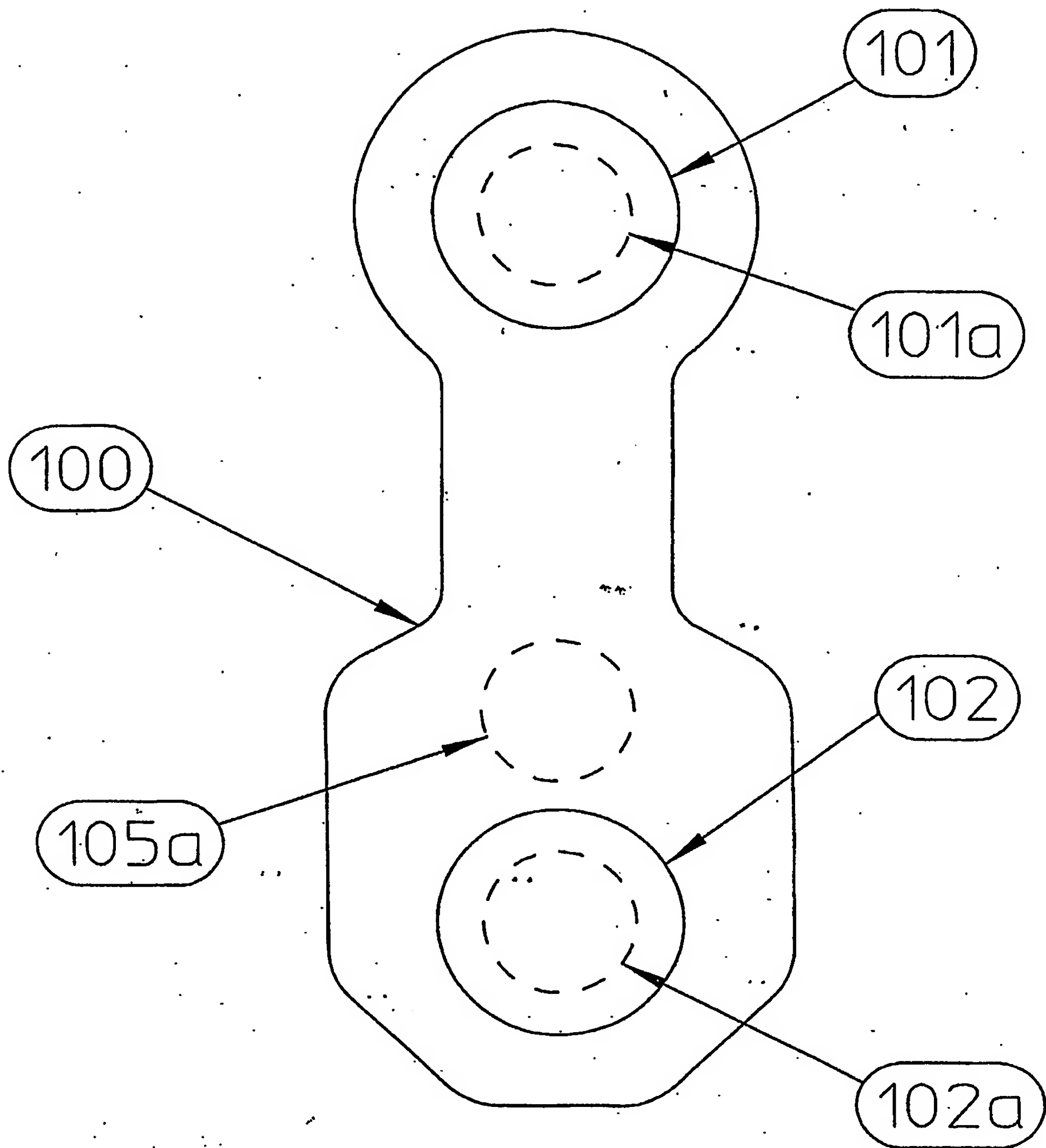


Fig. 1a  
PATIENT SIDE

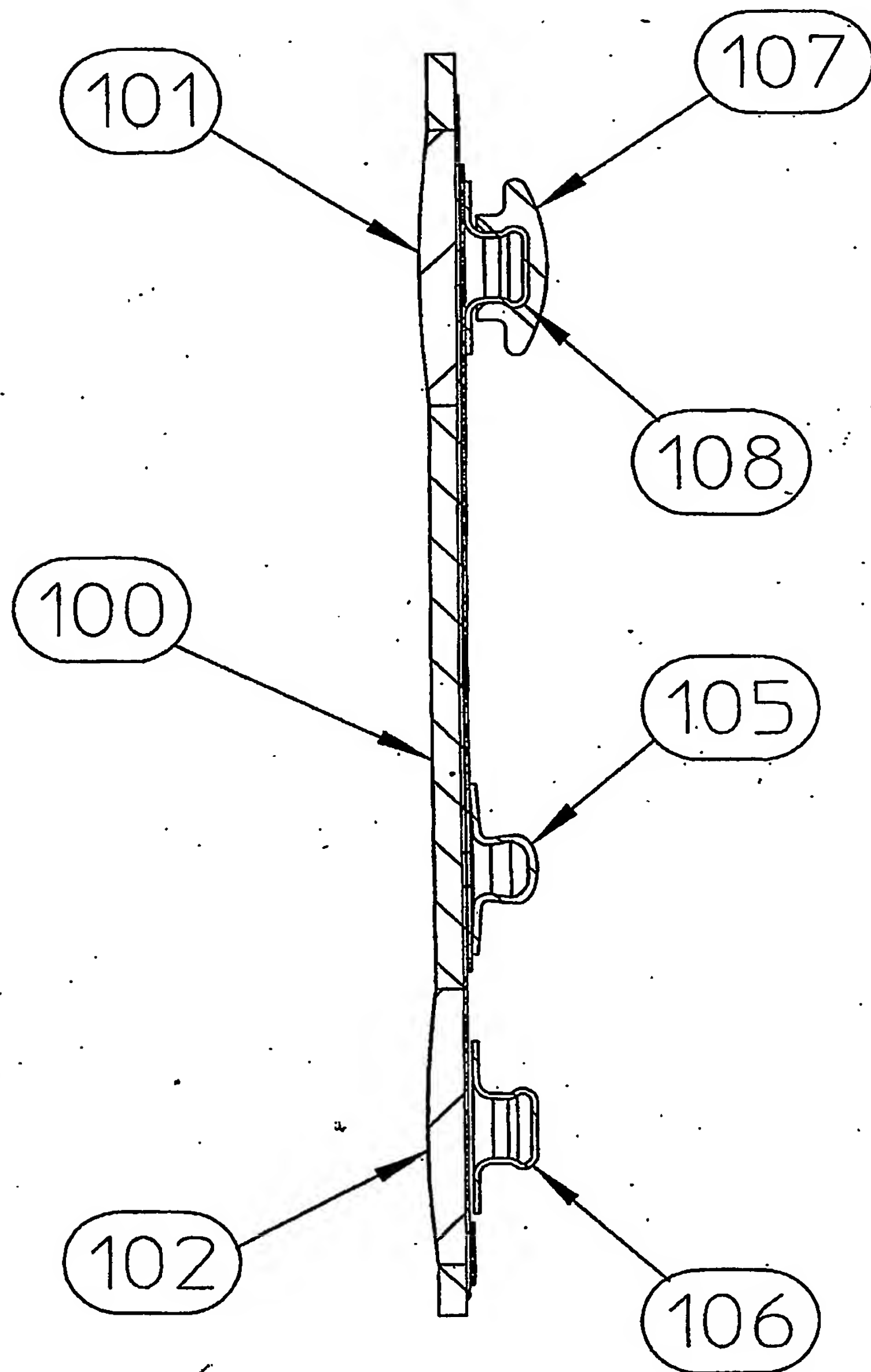


Fig. 1b  
CROSS-SECTION



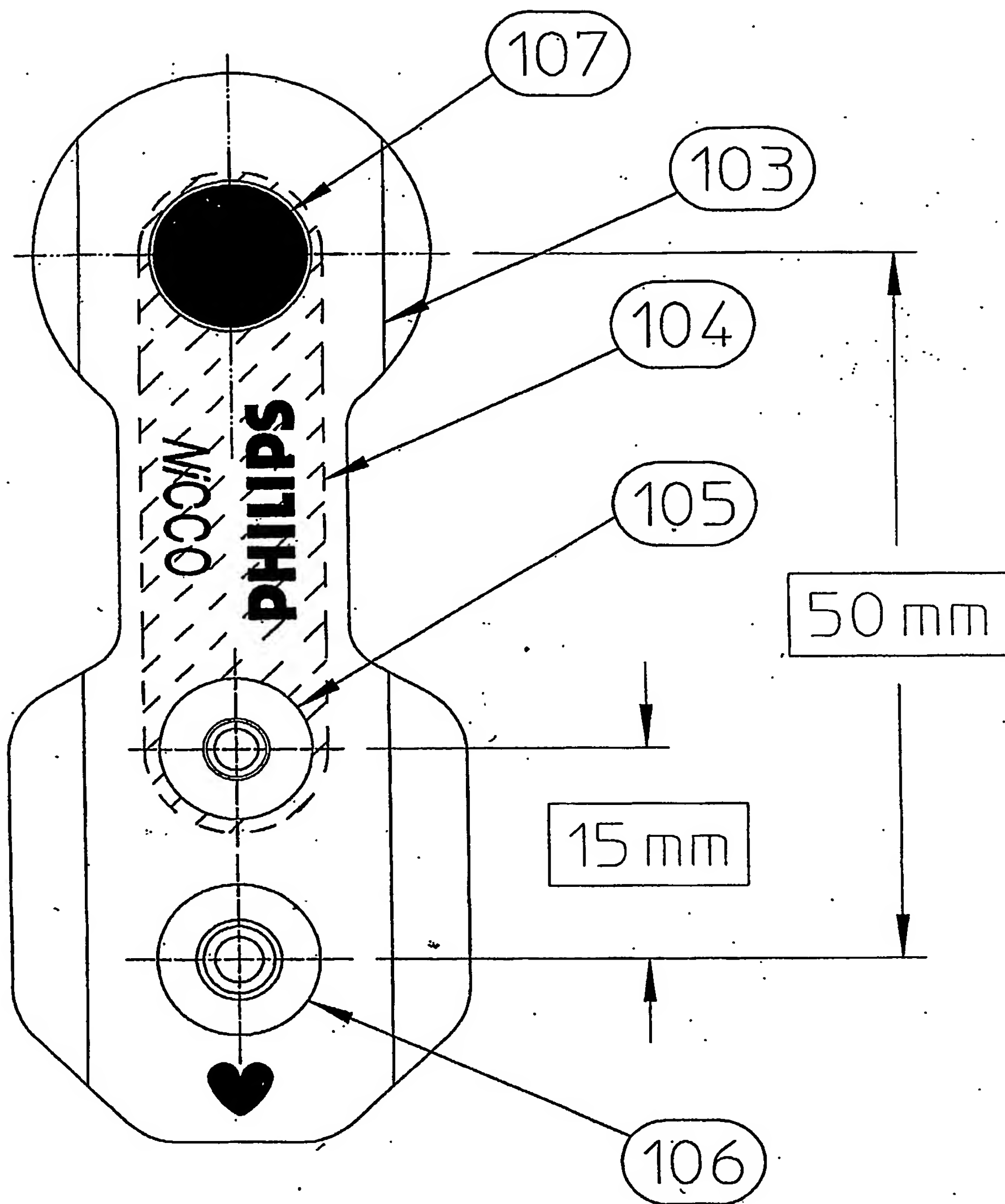


Fig. 1c  
CABLE SIDE

This Page is inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☒ COLORED OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REPERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images  
problems checked, please do not report the  
problems to the IFW Image Problem Mailbox**